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Outcomes of Aortic Valve Replacement 3 According to Surgical Approach in 3 **Intermediate and Low Risk Patients: A Propensity Score Analysis**

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| Q6 Q7 | Background | Previous trials have shown that, among high-risk patients with aortic stenosis, survival rates are similar for transcatheter aortic-valve implantation (TAVI) and surgical aortic valve replacement. The study aimed to compare the outcomes of aortic valve replacement according to the adopted surgical approach in intermediate and low risk patients. |
|----------|-------------|--|
| | Methods | This is a retrospective, observational, cohort study of prospectively collected data from 421 patients under- going isolated aortic valve replacement between 2011 and 2015. A multinomial logit propensity score model based on preoperative risk factors were used to match patients 1:1:1 between conventional replacement (CAVR), minimally invasive (MIAVR) and TAVI groups, resulting in 50 matched three cohorts. |
| | Results | After multinomial logit propensity score, the three groups were comparable in terms of preoperative characteristics. Mean age and Logistic EuroSCORE I of CAVR, MIAVR and TAVI groups were (84.2 ± 5.1 vs. 82.3 ± 4.8 vs. 85.6 ± 4.9 years; p = 0.002) and ($11.4 \pm 3.6\%$ vs. $8.3 \pm 3.4\%$ vs. $15.8 \pm 5.4\%$; p < 0.001) respectively. Overall mortality rates were similar for the three patient cohorts at one year. There were no significant differences related to stroke to 30 days. In the TAVI cohort, pacemaker implantation for newonset total atrioventricular block became necessary in 30% of patients (p < 0.001) and 16% of patients had some degree of paravalvular aortic regurgitation, which was more than mild (p < 0.001). Total length of stay was shorter in the TAVI group when compared with surgical groups (11.5 ± 5.3 vs. 10.1 ± 6.9 vs 8.5 ± 3.7 days; p = 0.023). After discharge, the survival rate follow-up (average follow up: 46.7 months) was 70%, 84% and 72% for three cohorts (log Rank $x^2 = 2.40$, p = 0.3). |
| | Conclusions | In our experience, the three aortic valve replacement approaches offer very good results. Differences in the rate of complications were found between groups. Depending on patient's characteristics the Heart-Team group must offer the best surgical approach for each patient. |
| | Keywords | Aortic valve replacement • Minimally invasive surgery • Transcatheter aortic valve implantation |

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15 Introduction

16 **Q8** The techniques used in minimally invasive cardiac surgery (MICS) have undergone numerous changes in recent years. 17 18 Interest in laparascopic surgery in general drove the search for minimally invasive techniques which could be used in 19 cardiac surgery. It was Cosgrove, for example, who 20 21 described the first MICS in 1996 [1]. Since then, numerous 22 retrospective studies have reported extensive lists of patients 23 undergoing MICS [2-4], as well as comparisons with conventional techniques [5]. It has even been suggested that 24 25 patients who are high risk according to their EuroSCORE, can be feasible candidates for MICS in aortic valve replace-26 09 27 010 ment (AVR) [6].

The decision to operate on a patient of advanced years entails a number of specific problems relating to the increase in mortality and operational morbidity [7]. The extraordinary technological advances in cardiology over the last few years – particularly since the introduction of transcatheter aortic valve implantation (TAVI) – have made it possible to tackle aortic stenosis in patients who previously would not have undergone any type of surgical intervention [8,9].

35 Current European and American Guidelines, as well as the 36 US Food and Drug Administration (FDA) protocols, indicate 37 that TAVI is the treatment of choice in "inoperable" patients 38 and a valid option to surgical AVR in patients judged to be at 39 high risk for surgery by a multidisciplinary team. Over the 40 years, TAVI has become more and more popular and similar 41 to what happened after the emergence of coronary stenting 42 procedure, there has been a trend in clinical practice to treat "lower" risk patients, the so called "grey zone" group of 43 44 patients.

For all of the above, we consider it necessary to analyse the various surgical options for the treatment of aortic 45 valve stenosis. Historically, aortic valve replacement is 46 47 performed by complete median sternotomy. Nowadays, however, other approaches are available, such as mini-48 mally invasive surgery [1] and percutaneous therapies 49 which avoid sternotomy and cardiopulmonary bypass, 50 51 which aim to be alternatives to surgery. The aim of this study was to compare results of aortic valve replacement 52 53 regarding the surgical approach in intermediate and low 54 risk patients in our institution.

55 Materials and Methods

56 **Patient Selection**

This was a retrospective, observational cohort study of prospectively collected data from 425 consecutive patients with aortic valve disease who underwent isolated AVR in our centre between January 2011 and December 2015. Of these, 296 (70.3%) AVR were performed through conventional replacement (CAVR), 75 (17.9%) through MIAVR by mini sternotomy and 50 (11.9%) through TAVI using CoreValve[®] prosthesis (Medtronic, Minneapolis, EEUU). Patients were considered to belong to intermediate and low surgical risk categories on the basis of the clinical assessment by our Heart Team considering an estimated Logistic EuroSCORE below 20%, as it was in the high risk cohort sub-analysis of the Placement of Aortic Transcatheter Valve (PARTNER) trial. Included in the study were all patients admitted for elective aortic valve replacement surgery and patients for whom aortic valve replacement was indicated under current European Society of Cardiology (ESC) and American Heart Association (AHA) guidelines. Patients who required other, concomitant procedures (coronary or valvular surgery, or surgery of the ascending aorta or the aortic arch), patients who had previously undergone cardiac surgery or had undergone mediastinal radiation were excluded. A multinomial logit propensity score model based on preoperative risk factors were used to match patients 1:1:1 between CAVR, MIAVR and TAVI groups, resulting in 50 matched three cohorts. Patients were only included in the analysis if suitable matches were found across the three approaches groups.

Surgical Procedure

Minimally Invasive Aortic Valve Replacement

The patient was placed in the supine position, anaesthetised and intubated with a single lumen endotracheal tube. A transeosophageal echocardiographic Doppler probe was then placed intraoperatively to assess the anatomy of the diseased valve. A 6–8 cm incision was made beginning 2 cm above the angle of Louis. The sternum was then opened from the sternal notch to the third or fourth intercostal space and extended rightward, severing the sternum.

Cold-blood cardioplegic solution was used. This was given every 20 minutes by direct infusion into the coronary ostia. A cannula was sewn to the wound edge to enable flooding of the surgical field with carbon dioxide, in order to reduce air emboli. To enable the use of smaller venous cannulae, vacuum-assisted venous drainage was used. The aorta was cannulated for arterial return at the pericardial reflection. Normothermic CPB were used. Sutures with pledgets were used in replacing the aortic valve.

The lungs were inflated to expel air from the left ventricle and aorta prior to completing closure. Echocardiography was used to monitor the completeness of air removal. Two atrial and ventricular pacing wires were placed. A straight chest tube was inserted behind the sternum.

Transcatheter Aortic Valve Implantation

The patient was given a general anaesthetic. They were 109 under full monitor, including a cerebral oximeter and trans-110 oesophageal echocardiography. A transfemoral TAVI proce-111 dure was performed in the standard manner, using a surgical 112 cut-down to the ilio-femoral vessels and the transcatheter 113 aortic valve was delivered using an Introducer Set, following 114 which the standard balloon valvular dilatation was per-115 formed. The valve stent was then launched via femoral 116 artery. The CoreValve valve stent was deployed with rapid 117

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